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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/044,426 | 11/13/2001 | Helle Woldike | 5565.214-US | 3262 |
| 23650 | 7590 | 08/03/2004 | EXAMINER | |
| NOVO NORDISK PHARMACEUTICALS, INC 100 COLLEGE ROAD WEST PRINCETON, NJ 08540 | | | MARVICH, MARIA | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1636 | | |

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|-----------------|----------------|
| Advisory Action | Application No. | Applicant(s) |
| | 10/044,426 | WOLDIKE ET AL. |
| Examiner | Art Unit | |
| Maria B Marvich, PhD | 1636 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 3 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. Applicant's reply has overcome the following rejection(s): _____.
4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,4,5 and 7-10.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. Other: See Continuation Sheet


GERRY LEFFERS
PRIMARY EXAMINER

Continuation of 2. NOTE: The claims if amended as proposed in the amendment filed 7/14/04 raise issues of new matter. Applicants have amended claim 1 to recite a method for producing Factor VII using "an endoprotease having Kex2 activity". Applicants have indicated that support for this amendment is found in the specification at page 3, lines 21-30 and through the disclosure of three examples of proteins having Kex2 enzymatic activity- Kex2 itself, a carboxyterminally-truncated form of Kex2; and a Kex2 to which has been added an endoplasmic reticulum-specific retention signal. The passage at page 3, line 21-30 teaches that Kex2 is an endoprotease that cleaves at the C-terminus of Arg-Arg, Lys-Arg and Pro-Arg sequences and is a glycoprotein of 100 to 120 KD. While the passages and the three examples teach Kex2 endoprotease and two modifications to Kex2, there is no literal support in the originally filed specification for the term "endoprotease having Kex2 enzymatic activity". Therefore, this limitation is impermissible NEW MATTER. Furthermore, the amendment to claim 1 changes the scope of the method for producing Factor VII by using a Kex2 derived endoprotease wherein said endoprotease is at least about 90% homologous to Kex2 and exhibits Kex2 enzymatic activity to an endoprotease having Kex2 enzymatic activity. Thus, the amendment changes the scope of the claims and as such raises new issues requiring further consideration and a prior art search.

Continuation of 5. does NOT place the application in condition for allowance because: the applicant's arguments are moot in view of the non-entry of the after final amendment..

Continuation of 10. Other: Applicants have not amended claim 1 to overcome the rejection under 112, second paragraph for lacking antecedent basis in recitation of "said variant"..